

STATE OF CALIFORNIA
FISH AND GAME COMMISSION
AMENDED INITIAL STATEMENT OF REASONS FOR REGULATORY ACTION
(Amended Pre-publication of Notice Statement)

Add new Section 1.92, add new subsection (c)(11) of Section 671, and add new
subsection (a)(9) of Section 671.1
Title 14, California Code of Regulations

Re: Define the term Transgenic, add transgenic aquatic animals to the list of live
animals restricted for importation, transportation and possession, and add conditions for
issuing permits for transgenic aquatic animals.

- I. Date of Initial Statement of Reasons: November 4, 2002
Date of Amended Initial Statement of Reasons: November 26, 2002
- II. Dates and Locations of Scheduled Hearings:
 - (a) Notice Hearing: Date: October 25, 2002
Location: Crescent City
 - (b) Discussion Hearing: Date: December 6, 2002
Location: Monterey
 - (c) Adoption Hearing: Date: February 6, 2003
Location: Sacramento
- III. Description of Regulatory Action:
 - (a) Statement of Specific Purpose of Regulation Change and Factual Basis
for Determining that Regulation Change is Reasonably Necessary:

Transgenic species are an example of bioengineered products that are produced under artificial conditions with the goal of enhancing yield or some other economically important biological trait. For example, many US agricultural plant crops include bioengineered varieties that are resistant to insects or viruses. Transgenic manipulation involves transferring genetic material (DNA) from one organism into chromosomes of another (generally species to species). The resulting genetic makeup is unique and the transgenic organisms have no genetic counterparts in natural systems. Because of their novel genetic structure, transgenic species should be considered “non-indigenous”, and potentially detrimental to native species.

There are no transgenic animals currently approved for agriculture production in the US. Research, development, and commercial use of

transgenic organisms are currently governed at the Federal level. For use of transgenic animals beyond confined laboratory research, (that is for production, sale, and distribution) approval must first be obtained from the Federal Food and Drug Administration (FDA). FDA has taken the position that transgenic animals contain a new animal drug that must be FDA approved before they may be used commercially. The requirement for FDA approval of new animal drugs applies to both food and non-food animals. The National Environmental Protection Act (NEPA), provides for environmental assessment as part of the drug approval process and provides the mechanism for coordination with other federal agencies. FDA is currently evaluating an application for transgenic Atlantic salmon for human consumption and is consulting with NMFS, USFWS and EPA in review of potential environmental impacts that might result if that application is approved.

Even though there is no current opportunity, outside of the research community to produce transgenic fish, it is clear that there is both interest in developing these fish, and concern about potential environmental impacts. The California legislature considered legislation in 2002 that would have placed a moratorium on importation of transgenic animals into the State. This legislation did not succeed. Also expressing concern over the growing interest in production and distribution of transgenic organisms, the American Fisheries Society, an organization of fishery professionals, issued a policy statement regarding transgenic fishes that “advocates caution in uses of transgenic fishes . . .”, and that “introduction of such fishes into natural aquatic communities may cause ecological or genetic impacts.”

In view of the increasing interest and concern relative to transgenic animals, the Department recommends that the Commission consider regulations appropriate to monitor the use of transgenic fish in research and to impose restrictions on commercial uses appropriate to ensure against detrimental impacts to California’s fish and wildlife resources.

To make clear, and explicit, the authority to allow or deny use of transgenic fish species, the Department recommends that transgenic fish be added, as a general category, to the Commission’s list of restricted species in Section 671, Title 14, CCR. In addition, it is recommended that the terms and conditions for which the Department may issue a permit for transgenic aquatic animals be added to Section 671.1. The Department has already drafted changes to the [application form \(FG 789\)](#) used for live fish importation permits. The change will require applicants to disclose the transgenic nature of the fish applied for.

Permit terms and conditions center around containment of transgenic animals within secure facilities and prevention of their escape or placement into waters of the State. Because of the uniqueness of building configuration, plumbing and security methods of each facility that may hold transgenic animals, permit authorization will be based on site inspections that consider the identified terms and conditions.

Because of potential adverse ecological impacts that may be caused by establishment of transgenic animals in waters of the State, penalties for unauthorized releases of transgenic animals are referenced from Fish and Game Code sections pertaining to illegal importation of restricted animals, and the importation of live aquatic animals without prior approval by the Department (Fish and Game Code sections 2152, 12007, and 12023). The maximum penalty identified for violation of these code sections is a fine of \$5,000 and up to one year in jail.

With the intent of informing the public of those facilities permitted to import, possess, or transport transgenic aquatic animals, the Department will provide the Commission with information regarding each restricted species permit application or aquaculture registration that has been approved or is under consideration for transgenic species.

In developing the definition of transgenic as used in the context of these regulations, the Department has considered the recommendations and technical expertise of interested persons from the Department, academia, legislature representatives, the aquaculture industry, organizations concerned with natural resource issues, and other interested parties.

- (b) Authority and Reference Sections from Fish and Game Code for Regulation:

Authority cited: Sections 200, 1002, 2118, 2120, 2122, 2150, and 2150.2 Fish and Game Code.

Reference: Sections 200, 1002, 2116-2118, 2118.2, 2118.4, 2119-2155, 2190, 2271, 3005.9, 3005.92 and 12007, Fish and Game Code.

- (c) Specific Technology or Equipment Required by Regulatory Change: None.
- (d) Identification of Reports or Documents Supporting Regulation Change: None.
- (e) Public Discussions of Proposed Regulations Prior to Notice Publication:

Dates and Locations of Scheduled Hearings:

October 18, 2002, Fisheries Programs Branch, 1812 9th St., Sacramento, California

November 18, 2002, Fisheries Programs Branch, 1812 9th St., Sacramento, California

IV. Description of Reasonable Alternatives to Regulatory Action:

- (a) Alternatives to Regulation Change:
Establish a moratorium on the importation or possession of all transgenic aquatic animals within the State for an indefinite period.
- (b) Consideration of Alternatives: A moratorium on the importation or possession of transgenic aquatic animals would ensure the protection of natural aquatic animal populations within the State. However, a moratorium would prevent research and the subsequent discovery of potential benefits that transgenic species may provide.

V. Mitigation Measures Required by Regulatory Action:

The proposed regulatory action will have no negative impact on the environment; therefore, no mitigation measures are needed.

VI. Impact of Regulatory Action:

The potential for significant statewide adverse economic impacts that might result from the proposed regulatory action has been assessed, and the following initial determinations relative to the required statutory categories have been made:

- (a) Significant Statewide Adverse Economic Impact Directly Affecting Businesses, Including the Ability of California Businessmen to Compete with Businesses in Other States: The proposed action will not have a significant statewide adverse economic impact affecting businesses, including the ability of California businesses to compete with businesses in other states. The proposed change will provide for continued research and development of transgenic aquatic organisms under safeguards appropriate to protect the wildlife resources of the State.
- (b) Impact on the Creation or Elimination of Jobs Within the State, the Creation of New Businesses or the Elimination of Existing Businesses, or the Expansion of Businesses in California: None.
- (c) Cost Impacts on Private Persons: The agency is not aware of any cost impacts that a representative private person would necessarily incur in reasonable compliance with the proposed action.

- (d) Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.
- (e) Other Nondiscretionary Costs/Savings to Local Agencies: None.
- (f) Programs Mandated on Local Agencies or School Districts: None.
- (g) Costs Imposed on Any Local Agency or School District that is Required to be Reimbursed Under Part 7 (commencing with Section 17500) of Division 4: None.
- (h) Effect on Housing Costs: None.

Updated Informative Digest/Policy Statement Overview

Transgenic species are an example of biotechnological products that are produced under artificial conditions with the goal of enhancing yield or some other economically important biological trait. For example, some aquaculturists are interested in creating a transgenic fish product that grows faster than a natural fish. Transgenic manipulation involves incorporating genetic material (DNA) from one ~~species~~ **organism** into chromosomes of another. The resulting genetic makeup is unique and these biotechnologically constructed organisms have no genetic counterparts in natural systems. Because of their novel genetic structure, transgenic species should be considered “non-indigenous”, and potentially detrimental to native species.

To make clear, and explicit, the authority to allow or deny use of transgenic fish species, the Department recommends that transgenic fish be added, as a general category, to the Commission’s list of restricted species in Section 671, Title 14, CCR. **In addition, it is recommended that the terms and conditions for which the Department may issue a permit for transgenic aquatic animals be added to Section 671.1(a).** The Department has already drafted changes to the [application form \(FG 789\)](#) used for live fish importation **permits**. The change will require applicants to disclose the transgenic nature of the fish applied for.

Permit terms and conditions center around containment of transgenic animals within secure facilities and prevention of their escape or placement into waters of the State. Because of the uniqueness of building configuration, plumbing and security methods of each facility that may hold transgenic animals, permit authorization will be based on site inspections that consider the identified terms and conditions.

With the intent of informing the public of those facilities permitted to import, possess, or transport transgenic aquatic animals, the Department will provide the Commission with information regarding each restricted species permit application or aquaculture registration that has been approved or is under consideration for transgenic species.

In developing the definition of transgenic as used in the context of these regulations, the Department has considered the recommendations and technical expertise of interested persons from the Department, academia, legislature representatives, the aquaculture industry, organizations concerned with natural resource issues, and other interested parties.

State of California
The Resources Agency
Department of Fish and Game
1416 1812 Ninth Street
Sacramento, CA 95814
(916) 653-8262 445-3617

FOR DEPARTMENT USE ONLY

Pathologist _____ Phone _____ Permit No. _____
Date _____ Fee Rec'd _____ Check No. _____
Date of Health Certification _____

**APPLICATION FOR STANDARD IMPORTATION PERMIT – AUTHORIZATION TO SHIP
IMPORTED LIVE AQUATIC PLANTS OR ANIMALS INTO CALIFORNIA AND REQUEST FOR
HEALTH INSPECTION**

(Separate application required for each shipment)

Authority and Reference: Section 236, Title 14, California Code of Regulations

Transported by _____ Phone _____

Address _____
City State Zip Code

Source of Fish _____ Phone _____

Address _____
City State Zip Code

Consignee _____ Phone _____

Address _____ Phone _____

Fish to be inspected at _____

Date of shipment _____ Time of arrival at inspection point _____

Destination of fish _____
(if different from consignee) Name Address City Zip Code

Route will be via Highway No. _____

<u>Species</u>	<u>Number</u>	<u>Pounds</u>	<u>Transgenic Individuals</u>	
_____	_____	_____	<u>No</u> _____	<u>Yes</u> _____
_____	_____	_____	<u>No</u> _____	<u>Yes</u> _____
_____	_____	_____	<u>No</u> _____	<u>Yes</u> _____

Signed _____
Consignee

DO NOT WRITE BELOW – FOR OFFICIAL USE ONLY

Application reviewed by _____
Chief, ~~Wildlife Protection Division~~ Conservation Education & Enforcement Branch Date

Shipment inspected and approved by _____ Date _____
FG 789 (4/92/02)